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AIRLINES, DEFIBRILLATORS, AND ENHANCED MEDICAL KITS: FILLING A VOID OR CREATING A DUTY?

JULIE A. BUFFINGTON

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I. INTRODUCTION

IMAGINE YOURSELF embarking on a flight. Uncharacteristically, you arrived in plenty of time, boarded, and are now beginning to relax in anticipation of an uneventful three-plus hours. The plane is first for takeoff and races down the runway, soaring into the air. You recline upon reaching the cruising altitude of 35,000 feet.

Just when you are about to doze off, the man next to you starts to fidget. You do your best to ignore him, hoping he will settle down so you can rest. Then, because he begins to moan, you look over and witness the beginning of an in-flight emergency.

Once restless, the man is notably uncomfortable. He is very pale and perspiring heavily. You ask him if everything is all right, but he replies incoherently. Now alarmed, you press your call button to summon the flight attendant. But no one comes right away. All of the flight attendants are busy preparing for cabin service. You wait, silently witnessing the distress experienced by your traveling companion. It has not been that long since you pressed the call button, so you wait longer, obeying the still lit fasten-your-seat-belt sign and continue to worry as the minutes tick by . . .

The United States is world-renowned for its excellent health care system. This country is abundantly proud of the fact that medical assistance is available within minutes of most emergency situations. Now, some airlines have taken this service to the air. In an effort to save lives, one U.S. airline¹ and several interna-

¹ American Airlines was the first U.S. airline to equip overseas flights with portable defibrillators. See American Airlines, Inc., AMR Corp. Communications, *American Airlines To Put Defibrillators on Aircraft* (visited Aug. 26, 1997) <<http://>

tional airlines² have taken the unprecedented step of equipping certain aircraft with cardiac defibrillators.³

The objective of this Comment is to assess the legal implications surrounding an airline's decision to provide additional in-flight emergency medical care services. Specifically, this Comment analyzes the scope of the duty of care issue with respect to an air carrier's decision to equip its planes with portable defibrillators or, alternatively, not to take this step until required by law. According to the American Medical Association, airlines should be commended for providing this enhanced service.⁴ The American Medical Association demonstrated its support of American Airlines's decision to equip certain planes with defibrillators by sponsoring the airline's conference on defibrillation. At the conference, the air carrier stated that "'sudden cardiac events [are the] most common in-flight event, and are a major cause of medical (aircraft) diversions.'"⁵

The American Heart Association's promotion of defibrillator access, like American Airlines's promotion, is premised on saving lives; if an air carrier's subsequent actions can prevent even a minute percentage of the millions of air travelers in this country from post-cardiac-arrest death then they will be providing an

www.amrcorp.com/amr/nov1996b.htm > [hereinafter AMR Corp. Communications]. According to Robert L. Crandall, American Airlines Chairman and chief executive officer, "[t]his . . . [was] a significant step in ensuring the health of our passengers." *Id.* Delta and United Airlines have also announced plans to equip their entire fleet beginning in July 1998. See Edwin W. Brown, *Medical Update: Flying More Friendly Skies*, MED. EDUC. & RES. FOUND., June 1998, at 3. All "three airlines expect to have their entire fleets capable of providing this emergency service" by year's end. *Id.*

² Qantas, Virgin Atlantic, and Air Zimbabwe presently carry defibrillators. See John Crewdson, *Survival in the Sky, FAA: In-flight Medical Emergencies Increasing*, CHI. TRIB. (visited Aug. 26, 1997) <<http://www.chicago.tribune.com/news/in-flight/051097.htm>>.

³ This step was in response to increased efforts from the medical community and travel agents to provide access to appropriate in-flight medical emergency equipment. See Susan Okie, *Doctors Complain Airplanes Lack Sufficient Medical Equipment*, WASH. POST, reprinted in DALLAS MORNING NEWS, Jan. 18, 1998, at 8A; see also Tom Belden, *Travel Agents Suggest Their Bill of Rights for Passengers On Airlines*, ST. LOUIS POST-DISPATCH, July 13, 1998, at 23.

⁴ See Joseph J. Cottrell, et al., *In-flight Medical Emergencies: One Year of Experience With the Enhanced Medical Kit*, 262 JAMA 653 (1989), available in 1989 WL 3078991.

⁵ Crewdson, *supra* note 2 (quoting American Airlines). According to American Airlines, "between 50 and 60 passengers a year are given cardiopulmonary resuscitation by flight attendants, [which is] currently the only treatment available for cardiac arrest" on U.S. domestic flights. *Id.*

invaluable service.⁶ American Airlines alone is responsible for over 80 million passengers.⁷

These added health precautions are welcome news to the traveling public. Surprisingly, this news may not be welcomed by the airline industry itself because these enhanced services may come with an unanticipated high price—a higher standard of care. As meritorious and humane as the American Medical Association's concept may seem, there are legal and non-legal issues that must be addressed in deciding whether to provide, or more importantly, not provide enhanced medical care services in the sky.

Public policy considerations have generated tremendous support for enhanced medical care. Congress has acted to eliminate some major legal hurdles for airlines and individuals attempting to provide medical assistance for in-flight medical emergencies. Specifically, the Aviation Medical Assistance Act of 1998 (Aviation Act) provides liability limits for both the air carrier and qualified medical professional aiding passengers in need.⁸ The Aviation Act also provides for the issuance of additional regulations regarding mandatory medical equipment, as well as mandatory training requirements, following a one-year assessment of in-flight deaths that were potentially avoidable given the availability of enhanced in-flight medical care.⁹ This is a dynamic area of regulation that must be monitored carefully in order to ensure compliance.

Until mandatory requirements are issued, an air carrier must analyze the liability implications surrounding the decision to upgrade its in-flight medical services. This involves assessing several areas in order to evaluate the carrier's potential liability for this changing area of regulation. First, an air carrier must address present regulatory issues. Among these are the questions of whether a defibrillator is a regulated medical device and whether a flight attendant or Good Samaritan may perform

⁶ See AMR Corp. Communications, *supra* note 1. The American Heart Association "estimates that 100,000 lives a year could be saved if AEDs [Automatic External Defibrillators] were broadly deployed in areas where large groups of people gather, such as on aircraft." *Id.*

⁷ See John Crowdsen, *1st Airline in U.S. Adds Heart-Saving Equipment Defibrillators Could Save Scores of Lives*, CHI. TRIB., Nov. 17, 1996, available in 1996 WL 2727757 (Passenger figures reflect 1995 records). Delta was the carrier with the most passengers at 87 million. See *id.*

⁸ See Aviation Medical Assistance Act of 1998 §§ 5(a)-(b), 49 U.S.C.A. § 44701 (West Supp. 1998).

⁹ See *id.* §§ 2-4.

defibrillation. Second, negligence and assumption of duty issues must be analyzed. This includes exploration into the key standard of care issue: By providing this service, thereby acknowledging this need, is an airline assuming a duty to provide advanced medical care to its passengers? If so, has this increased the standard of care? Third, when an air carrier restricts this service to limited flights, is that airline neglecting its duty to passengers on its other flights?¹⁰ Fourth, when one airline provides this level of service, has it effectively put all other airlines on notice, thus requiring all airlines to follow the state of the art? Finally, the airline must analyze product liability and preemption of state and federal law issues to determine the extent of an airline's potential exposure in equipping its planes with defibrillators.

Part II of this Comment explores the requisite medical foundation—by providing the medical guidelines for emergency cardiac resuscitation, explaining what defibrillators are, and demonstrating the benefit and necessity of early defibrillation—and applies this information to the context of air carriers. Part III discusses the federal regulation of medical devices with respect to the particular type of defibrillator at issue and the resulting potential liability. This part explores the procedures a device manufacturer must follow as well as the broad latitude a device manufacture enjoys in getting its product to market through the FDA approval process. Part IV addresses aviation use of defibrillators and enhanced medical kits. An air carrier's compliance with both FAA and FDA regulations are explored as well as the personnel limitation that results from use of defibrillators. Part V provides a legal assessment of the affirmative act of an airline treating passengers with defibrillation. This part provides an analysis of the liability implications as a result of the Aviation Medical Assistance Act of 1998. Part V also explores an airline's basic defibrillation policy, superimposing the emergency cardiac resuscitation guidelines and realistic assumptions that can be relied upon if an airline chooses to employ a less-than comprehensive treatment program for ill passengers. Part

¹⁰ See John Crewdson, *Code Blue: Survival in the Sky. Crucial Moments after a Cardiac Arrest*, CHI. TRIB., June 30, 1996, available in 1996 WL 2685952. This issue was raised in Crewdson's Chicago Tribune series reporting on airlines' use of defibrillators. "[S]ome airlines fear they might open themselves to negligence lawsuits if they limit defibrillators to some flights . . . [because] they're acknowledging a concern and a responsibility," therefore, potential liability may exist by equipping only a portion of their fleet. *Id.*

VI addresses international preemption issues and reviews the common law for liability situations analogous to an airline's in-flight emergency medical care treatment policy. This part examines the underlying duty-of-care issue and the issue of whether voluntary acts, as a result of a common carrier's internal policies, create a heightened duty. The analysis assesses this issue utilizing a comparative analogy of both airline and common carrier applications of tort law. Part VI provides recommendations that will allow an air carrier to balance the competing concerns of providing adequate in-flight emergency medical assistance while minimizing both the legal and non-legal costs of providing this service. In conclusion, Part VIII provides encouragement—from this potential recipient of in-flight emergency aid—to air carriers to fully deploy defibrillators and expanded medical kits on every airplane.

II. MEDICAL FOUNDATION — CARDIAC HEALTH ISSUES

Heart disease is the number one killer in the United States.¹¹ With over 737,500 victims claimed in 1995, it is easy to understand why members of the medical community have long advocated "more accessible defibrillation" for all public places.¹² It is well accepted that early defibrillation can give a heart attack victim a second chance at life.¹³ Prior to the advent of modern medical treatment, sudden death was the invariable result when ventricular fibrillation occurred outside a hospital.¹⁴ Defibrillation, one example of modern treatment, has established its value in treating certain cardiac emergencies.¹⁵

¹¹ See Mark Clements & Dianne Hales, *How Healthy Are We?*, PARADE MAG., Sept. 7, 1997, at 4.

¹² Crewdson, *supra* note 7; see also W. Douglas Weaver et al., *Use of the Automatic External Defibrillator in the Management of Out-of-Hospital Cardiac Arrest*, 319 N. ENG. J. MED. 661, 661-66 (1988). See generally Malcolm McConnell, *This Machine Could Save Your Life, So Why Isn't It Widely Available?*, READER'S DIGEST, Nov. 1997, at 69.

¹³ See Crewdson, *supra* note 7. Dr. Myron Weisfeldt, Chairman of Medicine at Columbia Presbyterian Hospital in New York City and past President of the Heart Association, believes that "early defibrillation alone can save lives" because experiments in several cities have done so by equipping police officers and firefighters with defibrillators alone. For example, in Seattle, where the average emergency response time has been cut to eight minutes, "the survival rate among some groups of patients is about 30 to 40 percent." *Id.*

¹⁴ See Peter Safar, *Mickey S. Eisenberg's Life in the Balance: Emergency Medicine and the Quest to Reverse Sudden Death*, 337 N. ENG. J. MED. 206 (1997) (book review).

¹⁵ See *id.* "In cases of cardiac arrest the best hope for survival, and often the only hope, is immediate defibrillation." Crewdson, *supra* note 10.

A. CARDIAC RESUSCITATION: ACCEPTED MEDICAL GUIDELINES

The role that defibrillation assumes in cardiac incidents is best understood within its context. Cardiac emergencies come in different forms, only one of which is ventricular fibrillation. "Ventricular fibrillation is the most common cause of cardiac arrest."¹⁶ Defibrillation is effective to remedy ventricular fibrillation.

Ventricular fibrillation, in layman's terms, is the condition that results when a person's heart beat goes out of sync. Scientifically, ventricular fibrillation is defined as "the sudden onset of chaotic electrical activity in the muscle wall of the ventricle, leading to disorganized quivering of the heart with no forward movement of blood."¹⁷ "Ventricular fibrillation is a very treatable disorder, in which a successful outcome is related to the time from onset to defibrillation."¹⁸ Thus, time is the most critical factor.

B. DEFIBRILLATOR OPERATION

The defibrillator operates, through external shock, to electrically stimulate the heart and restore its normal rhythm. Defibrillation is technically known as "electrical cardioversion."¹⁹ Electrical cardioversion is recognized as an effective method used to restore the heart's rhythm for certain, but not all, causes of fibrillation.²⁰ Again, timing is crucial. Unless "corrective measures are undertaken promptly" the patient will "usually terminate fatally within 3 to 5 minutes."²¹

¹⁶ Mayerline Michel, *Portable Units Give Hearts A Jump-Start*, SUN-SENTINEL, Aug. 15, 1998, at 1B. Nationwide, 350,000 people die as a result of ventricular fibrillation. See *id.* (citing the American Heart Association).

¹⁷ Paul C. Sorum, *Symposium on the Legal and Ethical Implications of Innovative Medical Technology: Limiting Cardiopulmonary Resuscitation*, 57 ALB. L. REV. 617, 617-18 (1994) (citing W.B. Kouwenhoven et al., *Closed-Chest Cardiac Massage*, 173 JAMA 1064 (1960); Arnold Sladen, *Closed-Chest Massage*, 251 JAMA 3137 (1984)).

¹⁸ Arthur L. Kellerman et al., *Automatic External Defibrillator For Out-Of-Hospital Cardiac Arrest*, 320 NEW ENG. J. MED. 670, 670-71 (1989).

¹⁹ HEART DISEASE: A TEXTBOOK OF CARDIOVASCULAR MEDICINE 651 (Eugene Braunwald ed., 4th ed. 1992) [hereinafter HEART DISEASE]. Doctor Braunwald's textbook is widely recognized among cardiologists as the authority in the field. Doctor Braunwald was the Chairman of Harvard Medical School.

²⁰ See *id.* There are several causes of "tachycardias" for which electroconversion "is not indicated." *Id.*

²¹ *Id.* at 709. This timeframe was confirmed by cardiologist Steven L. Shilling, whom I thank for verifying the medical foundation of this Comment. Interview with Steven L. Shilling, M.D., F.A.C.C., in Irving, Tex. (Aug. 29, 1997) (on file with author) [hereinafter Shilling]. Another source provides a slightly more op-

The overarching objective in a ventricular fibrillation scenario is to restore normal heart function quickly. After doing so, it is critical that the patient receive immediate follow-up treatment as provided in the medical guidelines set forth by the American Heart Association.²² Importantly, this follow-up treatment is not optional. Once the immediate crisis is over, the actual underlying medical issue that initially caused the heart to fibrillate must be remedied. If the underlying problem is not corrected, there is a substantial risk of a recurrence of ventricular fibrillation or death.²³ Medical experts agree that “[v]entricular fibrillation rarely spontaneously terminates and death results unless countermeasures are instituted immediately. Subsequent therapy is necessary to prevent a recurrence.”²⁴

One thing is very clear: without *early* defibrillation, a victim’s *opportunity* to receive subsequent treatment will literally pass. Medical experts warn that the electrical shock must be administered immediately and “[t]ime should not be wasted with cardiopulmonary resuscitation maneuvers if electrical defibrillation can be done promptly. It is important to reemphasize that there should be no delay in instituting electrical shock.”²⁵ Administered correctly, airlines providing defibrillators are affording passengers who experience in-flight ventricular fibrillation a second chance of survival.

C. PRELIMINARY ISSUE: TIMELY DEFIBRILLATION AND FLIGHT ATTENDANT DEMANDS

A preliminary issue with airline use of defibrillators is whether flight attendants, despite all their preexisting in-flight duties, will be able to meet the medical guidelines requiring immediate

timistic timeframe by stating that “victims need to be shocked in five to seven minutes to live. Each one-minute delay decreases the chance of survival by 10 percent.” Michel, *supra* note 16.

²² See Crewdson, *supra* note 7. “The American Heart Association’s defibrillation guidelines call for the use of epinephrine, lidocaine and other drugs in conjunction with electric shocks.” *Id.* Additionally, Congress has acknowledged the “Advanced Cardiac Life Support” guidelines, and the “[c]omplex procedures . . . [that] include the administration of drugs, electric shock, and intubation.” *Guidelines for State Court Decision Making in Life-Sustaining Medical Treatment Cases: Coordinating Council on Life-Sustaining Medical Treatment Decision Making by the Courts*, Revised 2d ed., at App. C, available in 1993 WL LSMTCS APP C [hereinafter *Guidelines*].

²³ See HEART DISEASE, *supra* note 19. “Frequent complex ventricular arrhythmias are common during the first 48 to 72 hours after resuscitation.” *Id.* at 779.

²⁴ HEART DISEASE, *supra* note 19, at 710.

²⁵ *Id.*

response. For example, in the introductory hypothetical, the flight attendant is unable to respond immediately to the call button because of numerous competing in-flight demands. Realistically, these demands may mean that a flight attendant will be inaccessible for several minutes during boarding, take-off, cabin service, cabin preparation, landing, and numerous other emergencies and duties. Because of the demands of the position, it is entirely possible that flight attendants will not meet the immediacy requirement of the medical guidelines. But, without attempting to defibrillate, a patient's chances of survival in the instances where defibrillation could have been effective, are slight. Thus, it is understandable that advocates in the medical community support widespread accessibility to defibrillation.²⁶

1. *The Ten Minute Window*

American Airlines's corporate medical director, Dr. David McKenas states that "[w]ith each passing minute, the chance of survival by a sudden cardiac arrest victim decreases by 10 percent."²⁷ "If a shock can be administered within the first minute—something that is virtually impossible on the ground . . . the chances of survival approach 90 percent."²⁸ Whether this is a realistic time frame aboard an airplane is highly fact driven, but—assuming a uniform decline in chance of survival—it is easy for a lay person to calculate the window of opportunity to be less than ten minutes.²⁹

2. *Consequences of Delay*

Even this sub-ten minute opportunity to aid passengers comes with a price to the provider. This is because the price of failure to successfully resuscitate may be a wrongful death lawsuit.³⁰

²⁶ See Crewdson, *supra* note 7.

²⁷ AMR Corp. Communications, *supra* note 1, at 1.

²⁸ Crewdson, *supra* note 7. "Even if passenger and defibrillator are at opposite ends of a Boeing 747 the time from collapse to defibrillation is likely to be well under the optimum of five minutes. . . ." *Id.*

²⁹ The math is as simple as ten times ten.

³⁰ For a complete discussion see §§ V-VI *infra* notes 89-73 and text accompanying notes. The new limits on liability provided by the Aviation Act do not shield an *individual* attempting to provide in-flight medical assistance from "gross negligence or willful misconduct." Aviation Medical Assistance Act (AMAA) of 1998 § 5(b), 49 U.S.C.A. § 44701 (West Supp. 1988). The issue becomes whether inadequate response time—given an airline's awareness of the ten-minute window and timely-response training for its flight attendants—would rise to the level of gross negligence. Notably, the air carrier itself is not liable for "acts or omissions"

The majority of lawsuits filed for medical malpractice result from failure to diagnose a heart condition.³¹ This fact is not surprising when you consider that cardiac conditions are also the most difficult to diagnose.³² Thus, lawsuits based on either or both theories of wrongful death and negligence are often products of surprise to the victims or their families and even to the best and brightest of doctors. The difficulty in detecting certain less-than-obvious medical problems makes it entirely possible that neither of the parties—doctor nor patient—would have suspected that a heart condition existed.

The diagnostic difficulty is the result of a myriad of nebulous symptoms that alone may seem innocent. Cardiac conditions are difficult to diagnose in some medical settings because even a normal "strip" from an electrocardiogram (EKG) cannot be taken as a green flag.³³ Some symptoms can indicate either indigestion or a serious heart problem and some cardiac conditions must be caught in the act in order to be detected.³⁴ This difficulty in detection results from the fact that a heart must be malfunctioning at the time the patient is monitored in order to be properly assessed. The rest is guess-work. Consequently, some people may indeed have a heart condition but still be totally unaware because their transient symptoms have evaded evalua-

under the act; however, because some airlines have also agreed to indemnify their flight attendants for the use of defibrillators, the airline would ultimately suffer the consequences. See Aviation Medical Assistance Act § (5)(a); see also Telephone Interview with John Hotard, AMR Corporate Community Speaker (Aug. 29, 1997) (on file with author) [hereinafter Hotard]. Interestingly, this may not concern most defibrillator providers because some portable defibrillator manufacturers, in an effort to encourage the sale and use of their products, are providing indemnification to anybody who buys their devices. See Rodd Zolkos, *Defibrillators Save Lives But May Create Liability*, BUS. INS., Aug. 10, 1998, at 3.

³¹ See Don Colburn, *Heart Attack Cases Top Claims for Malpractice*, WASH. POST, May 21, 1996, at 25, available in 1996 WL 3080720. The authority for this health law article was a study conducted by an insurance trade association finding that the most common problems were *delays in hospital treatment and follow-up procedures* "or *delay in use of drugs* to treat the heart attack." *Id.* (emphasis added).

³² See Braunwald, *supra* note 19, at 756. Symptoms "may occur during a period of weeks before a cardiac arrest, [and] tend to be nonspecific for the impending event." *Id.* "In 91 percent of the cases, doctors did not make the correct initial diagnosis, often because the symptoms resembled those of other diseases. Those symptoms included pain or pressure in the chest, shortness of breath, general weakness, coughing, fever and chills." Colburn, *supra* note 31.

³³ See, e.g., *Snia v. United Medical Center of New Orleans*, 637 So. 2d 1290 (La. Ct. App. 1995) (finding of no negligence in patient's death when EKG was normal and doctor could not tell if patient was suffering from an asthma attack or a heart attack).

³⁴ See *id.* at 1294.

tion. This can result in either the patient not seeking medical treatment, or the cardiac condition itself not malfunctioning at the time medical assistance is sought.

The above medical context underscores the gravity of cardiac emergencies and the importance of defibrillator accessibility. The proper assessment of a cardiac condition requires a comprehensive medical background that includes knowledge of masquerading symptoms, the use and limitations of portable defibrillators, and, in particular, the time constraints involved. This assessment literally must be done in seconds because, by the time a passenger is attended, little time will remain given the minutes that have already passed.

Intermittent symptoms may lead to a decision to forgo an otherwise necessary emergency landing. Would the above recommendation, by someone with training that includes the above information, rise to the level of gross negligence or willful misconduct when it is later determined that the passenger was indeed suffering from a heart attack? This concern is particularly relevant for those airlines intending to use defibrillation technology to avoid emergency diversions when the indication from the defibrillator is that all is clear.³⁵

III. FEDERAL REGULATION OF MEDICAL DEVICES

The automatic external defibrillator (AED) is the type of defibrillator the airlines use. It is a modern version of the original defibrillator with technology that first came on the scene in Europe in the mid-1940s.³⁶ The AED is a light-weight, battery

³⁵ See Crewdson, *supra* note 2. Indeed, it has been stated that this is an additional benefit of carrying defibrillators. Because defibrillator models used by the airlines can also provide an initial reading of the heart rhythm, some airlines may believe they can also benefit by averting emergency landings when this initial reading appears normal. Qantas is one example where the airline has used the defibrillator to determine if an emergency landing is necessary. See *id.* In conceding that not all defibrillations will be successful, Qantas wants to rely on defibrillator readings to confirm that unfortunate outcome and continue on course. See *id.* The Australian cardiologist "working closely" with Qantas stated that "forgoing emergency landings in cases where defibrillation had been unsuccessful might save the international aviation community more than \$6 million a year." *Id.* (emphasis added). At least Qantas is not suggesting that a successful defibrillation—or worse, a "normal" reading—precludes the need for an emergency landing. One fact is important: it is clear from the above discussion that emergency landings will still be required in either instance because follow-up emergency care with certain prescription drugs is a critical aspect of the advanced cardiac life support analog.

³⁶ See Safar, *supra* note 14.

operated, portable medical device that is easy to use. These features satisfy airline requirements and permit the device to be carried and used onboard planes.³⁷ The AED is considered a medical device and is subject to approval by the Food and Drug Administration (FDA).³⁸

A. THE MEDICAL DEVICE AMENDMENTS

The 1976 Medical Device Amendments established three medical device classes, each of which are subject to increasing levels of regulation.³⁹ Class I devices are subject to general controls, which are applicable to all medical device classes.⁴⁰ General "controls include registration and listing requirements;⁴¹ good manufacturing practices compliance;⁴² records and reports requirements;⁴³ susceptibility to special remedies for violations,⁴⁴ including notification, banning, repair, replacement, or refund; and the general prohibitions against adulteration⁴⁵ and misbranding."⁴⁶ Accordingly, Class II and III medical devices are subject to these general controls as well as additional controls indicated by their specific classification.⁴⁷

B. THE AUTOMATIC EXTERNAL DEFIBRILLATOR CLASSIFICATION

The FDA divides "DC-defibrillator" products (AEDs) among the latter two classes according to the amount of energy they produce. This energy is expressed by the amount of joules or

³⁷ See Hotard, *supra* note 30. Per Mr. Hotard, American Airlines tested a "grocery cart full" of the various AED models to determine which would be easiest to use. *Id.* The battery is required to last for five years, but it will require more frequent recharging. See *id.*

³⁸ See 21 C.F.R. § 870.5300 (1997). These types of defibrillators are classified as "Cardiovascular Therapeutic Devices" under the regulation. See *id.* at § 870.

³⁹ Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

⁴⁰ See 21 U.S.C. § 360c (1994).

⁴¹ See § 360.

⁴² See § 360j(f).

⁴³ See § 360i.

⁴⁴ See § 360h.

⁴⁵ See § 351.

⁴⁶ JAMES O'REILLY, FOOD AND DRUG ADMINISTRATION § 18.05 (2d ed. 1993) (internal footnote numbers revised to match Comment footnote numbers); see also 21 U.S.C. § 352 (1994).

⁴⁷ See *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997).

watts per second of shock the AED can deliver.⁴⁸ Low-energy AEDs are those that deliver “a maximum of 360 joules of energy . . . through paddles placed . . . on the surface of the body.”⁴⁹ High-energy DC-defibrillators deliver a “shock of greater than 360 joules” in the same manner.⁵⁰ According to federal regulations, the former category of low-energy defibrillators is subject to Class II performance standards,⁵¹ and the latter category is subject to the more stringent Class III premarket approval standards.⁵² Both standards are designed to ensure that the medical device is safe and effective when used on humans.⁵³ The difference is due to the fact that Class III devices may pose potentially unreasonable risks of injury, therefore, are subject to the rigors of the general approval process prior to being marketed.⁵⁴

The specific AED that American Airlines has chosen is a low-energy defibrillator.⁵⁵ As a result, the AED is only subject to Class II performance standards.⁵⁶ This means that the product was not subjected to the same premarket approval standards as a higher-energy-emitting device from Class III. Despite this procedural difference, the specific classification of the AED is of little significance when the manufacturer chooses an alternate and speedier route of approval based on substantial equivalence.

C. ALTERNATE APPROVAL PROCEDURE: SUBSTANTIAL EQUIVALENCE

Substantial Equivalence is an alternate approval route that exists for those devices, like the AED, that are based on the earlier technology of devices that have already been on the market.⁵⁷

⁴⁸ See 21 C.F.R. § 870.5300 (1997); see also Heartstream, Inc., *The Background Behind Our Technology; Innovations in the Development of Therapy* (visited Sept. 9, 1997) <<http://www.heartstream.com/tech/tech3.htm>>.

⁴⁹ 21 C.F.R. § 870.5300(a).

⁵⁰ *Id.* § 870.5300(b).

⁵¹ See *id.* § 870.5300(a)(2).

⁵² See *id.* § 870.5300(b)(2).

⁵³ See *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997).

⁵⁴ See 21 U.S.C. §§ 360e, 360c(a)(2)(C) (1994).

⁵⁵ See AMR Corp. Communications, *supra* note 1. The AED is called the Fore-runner™ and is manufactured by Heartstream, Inc. of Seattle.

⁵⁶ See *Becton, Dickinson & Co. v. Food and Drug Admin.*, 448 F. Supp. 776, 778 (N.D.N.Y. 1978) (describing performance standards corresponding to each device class).

⁵⁷ See *Dutton v. Acromed Corp.*, No. 69332, 69333, 69358, 1997 WL 15248, *1-2 (Ohio App. Jan. 16, 1997) (holding that the medical device does not satisfy the substantial equivalence process).

This alternative approval route bypasses the premarket approval steps necessary for new devices on the theory that the new manufacturer is not changing the basic technology that was subject to the approval process, therefore, the new device is "substantially equivalent" in both design and function to a "predicate device."⁵⁸ For example, if a new device is basically a duplicate of an existing device with a different brand name, it can get to market via the FDA's substantial equivalence process. This method of approval was developed to resolve the tremendous backlog of new medical device approvals at the FDA. The logic is based on the following premise: because the original device is already being used safely on humans, then the "knock-off" must also be safe. The only flaw with this logic is that the original device may also have circumvented the rigors of new product testing.⁵⁹

In the case of AEDs, substantial equivalence is the most cost efficient method of approval. FDA regulations are liberal and even permit this shortcut when a device is technologically different as long as clinical data "demonstrates that the device is as safe and effective as a legally marketed device and [the substantially equivalent AED] . . . does not raise different questions of safety and efficacy than the predicate device."⁶⁰ As a result, under this alternative approval process, also known as the 510(k) or Premarket Notification process (named for the applicable section of the Medical Device Amendments), it is possible for a device manufacturer to get its product to market years earlier than would otherwise be possible.⁶¹

The applicable federal regulation stipulates what is to be included in the premarket notification submission.⁶² The regulation requires a manufacturer who desires to put its substantially

⁵⁸ 21 U.S.C. § 360c(f)(1)(A) (1994); see also 21 C.F.R. § 814.80 (1997).

⁵⁹ See Scott E. Sanders, *Product Liability: Getting to the Heart of the Matter: Medical Device Preemption Defense Skips a Beat as Plaintiffs Are No Longer Completely Precluded from Bringing State Product Liability Claims Against Medical Device Manufacturers*, 36 WASHBURN L.J. 319, 324-26 (1997) (discussing the concern of pre-Medical Device Amendment of 1976 "grandfathering" of medical devices that are later used as the basis for a new device's substantial equivalence).

⁶⁰ 21 U.S.C. § 360c(i)(1)(A)(ii) (1994). It is interesting to note that Heartstream, the manufacturer of the AED being used on American Airlines, claims in its literature to have "developed a proprietary waveform," which would be an example of new technology, but the AED received marketing clearance through substantial equivalence to existing AEDs. Heartstream Inc., *supra* note 48 (Biphasic Waveform).

⁶¹ See *Dutton*, 1997 WL 15248 at *2 (denying 510(k) because the device was not substantially equivalent).

⁶² See 21 C.F.R. § 807.87 (1997).

equivalent product to a new use to “include appropriate supporting data to show that the manufacturer has considered what consequences and effects the . . . new use might have on the safety and effectiveness of the device.”⁶³

IV. AVIATION USE OF AEDS

Whether the airline’s use of AEDs by flight attendants is considered a “new use” of the substantially equivalent device is subject to debate. A broad interpretation of the term “use” is consistent with the original use of AEDs: emergency treatment of cardiac arrest. Conversely, a narrow interpretation yields another possibility: because lay persons (flight attendants) will be the ones using the AEDs on airplanes, the actual use is different and could affect the safety and effectiveness of treatment.

A. *FAA v. FDA REGULATIONS*

The Federal Aviation Authority (FAA) noted similar concerns in its discussion of a final ruling on the required contents of airplane medical kits.⁶⁴ The present medical kit contents were established to “eliminate[] equipment and drugs which, if misused, could compromise the health of the passengers and the safety and security of the flight.”⁶⁵ The FAA modified the proposed requirements of the medical kits to exclude “all surgical instruments and controlled drugs” for the above safety reasons.⁶⁶ Notwithstanding the FAA’s caution, major airlines have plans to enhance their on-board medical kits to include additional prescription drugs in order to be consistent with the goal of equipping planes with AEDs: to eliminate unnecessary health

⁶³ *Id.* § 807.87 (g); *see also* Crewdson, *infra* note 103 (an airline’s application is arguably different).

⁶⁴ *See* 51 Fed. Reg. 1218, 1221 (1986). The approved emergency medical kits required contents are: Sphygmomanometer, Stethoscope, three Airways, four Syringes, six Needles, 1-50% Dextrose Injection, Epinephrine (two single doses), two Diphenhydramine HCl injections, ten Nitroglycerin tablets, and basic instructions. *See id.* at 1223. Notably absent is a scalpel. Although doctors have requested this instrument to be included in the medical kits reserved for their use, the FAA and the airlines have not done so because a scalpel may be used in a hijack situation or could cause more harm than good to a passenger. A similar argument can be made concerning a defibrillator’s shock when used to arm a potential hijacker.

⁶⁵ *Id.* at 1221.

⁶⁶ *Id.*

risks in not being able to aid fully a passenger in distress.⁶⁷ The present difference in the ability to render comprehensive medical assistance, given the availability of AEDs and present drugs, is that flight attendants are not permitted to administer prescription drugs. Thus, the passenger-patient's ability to receive the benefits of comprehensive medical treatment will depend on whether a licensed, medical professional is on board as a passenger and is additionally willing to render aid in the emergency.⁶⁸

B. *FAA vs. FDA—TRAINING ISSUES*

Training of the flight personnel who will be using the AEDs is critical to the ability to aid effectively a passenger in distress. Is an AED akin to a prescription drug, only to be administered by a licensed professional? Is it permissible for non-medical personnel to administer the shock of the AED? Both the AED manufacturer and the airlines argue that any risks of improper use are neutralized by proper training. Training issues for the manufacturer's personnel are covered in the "Good Manufacturing Process" part of the FDA regulation.⁶⁹ The 510(k) Summary for the AED examined in this Comment contained no mention of specific training for the defibrillator users.⁷⁰ Still, federal regulations clearly require notice in the 510(k) when a device "is

⁶⁷ Both American and Delta airlines have publicized their plans to enhance their on-board medical kits. See Statement of Denise C. Hedges, President, Association of Professional Flight Attendants, at the House Transportation and Infrastructure Committee Aviation Subcommittee (May 21, 1997), in Federal Document Clearing House Congressional Testimony, 1997 [hereinafter Hedges]; see also Okie, *supra* note 3 (regarding Delta's decision to expand its medical kit). American has "ordered 745 expanded medical kits . . . that includes [sic] prescription medicine, IV equipment and surgical instruments." *American Airlines Plots Course to Total Air Care*, MED. INDUS. TODAY, Mar. 9, 1998.

⁶⁸ Indemnification of Good Samaritans and an airline's ability to rely on a "medically qualified individual" were key motivations in passing the new Aviation Medical Assistance Act of 1998. Aviation Medical Assistance Act (AMAA) of 1998 § 5(b), 49 U.S.C.A. § 44701 (West Supp. 1998). Given the present staffing limitations, however, adequate administration of follow up care with prescription drugs, when supplied, depends on the presence of a Good Samaritan passenger who also happens to be a doctor.

⁶⁹ See 21 C.F.R. § 820.25(b) (1997). "Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities." *Id.*

⁷⁰ Because only non-confidential portions of the summary 510(k) form are available to the public, it is not known if the complete application included this information. See Telephone Interview with Carol Fedorcheck, FDA Medical Device Division Small Business Advisor (Oct. 21, 1997) (on file with the author).

intended for lay use where the former intended use was by health care professionals only.”⁷¹

FDA regulations only restrict the use of a medical device to medical specialists when it has a “potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use [are] not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and . . . ‘adequate directions for use’ cannot be prepared.”⁷² Generally, a Class II medical device would not rise to this level of regulation, especially when the device was approved through the 510(k) process. This is because this restriction is only justified by a formal finding by the FDA that the safety and effectiveness of the device requires “specific training or experience in its use.”⁷³ Accordingly, because no formal findings are ever made under the informal 510(k) procedure, the FDA does not restrict the use of the Class II AED.⁷⁴

The FDA 510(k) process only requires that the manufacturer establish that the device works in the environment proposed.⁷⁵ In airline use, this requirement could be met by a showing that the AED does not interfere with the airplane’s electronics.⁷⁶ Thus, once the FDA approves a 510(k), it is up to the product’s

⁷¹ 21 C.F.R. § 870.9(a) (1997). This rule applies to limitations of exemptions of premarket notification for Class I devices that would otherwise be exempt from this section. Likewise, the FDA would require a Class II manufacturer to disclose this difference in use so that the safety and effectiveness within this context can be evaluated. An air carrier may counter that because the AED’s use is under the guidance of a medical doctor, either on staff or by contract with the carrier, the flight attendant’s use would not be a “lay” use.

⁷² 21 C.F.R. § 801.109 (1997). This restriction would seem to fit the original defibrillator device with greater than 360 joules, but apparently not the AED, because a strong argument can be made that “adequate directions for use” can be prepared and the low joules emitted are safe. *Id.*

⁷³ 21 U.S.C. § 360e(1) (1994).

⁷⁴ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (citing *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995) (a finding of substantial equivalence is not a formal finding of safety nor an act of FDA approval)).

⁷⁵ See Fedorcheck, *supra* note 70.

⁷⁶ Because information regarding airline use was not included in the specific 510(k) summary for the Forerunner AED, it cannot be assumed that this requirement was in fact met. If it was not, the manufacturer could be held liable for adulteration by not complying with an applicable premarket approval requirement.

end-user to provide for proper staff training.⁷⁷ Liability for negligent use is the carrier's penalty for failure to train properly.⁷⁸

The AED is not classified as a "prescription device"; therefore, the device is not subject to specific performance standards and the extensive ramifications attending that classification.⁷⁹ Performance standards for flight attendants in the use of AEDs fall under their regular first-aid training as well as additional training provided by the carrier in the use of the AED.⁸⁰ The critical issue as to whether medical supervision is required when administering the shock of an AED is contingent on whether the device could harm a person. It appears that the answer is no. The low amount of joules emitted by the AED mitigates against harm because the shock is to be administered only when a patient is unconscious. The result is no pain, and accordingly, no harm accompanies the proper use of an AED. In contrast, an incorrect assumption regarding a patient's state of consciousness may indeed mean that a person would feel the jolt from the AED and experience a great deal of pain.⁸¹

⁷⁷ The FAA leaves training up to the individual airlines and does not even require C.P.R. training for flight attendants. See Okie, *supra* note 3, at 8A. Airlines do train their attendants to administer C.P.R., but this is not required by the FAA. Of course, each state may have its own statutes covering training, depending on the intended application (for example, specific emergency medical training for paramedics).

⁷⁸ Gross negligence is now the standard. See Aviation Medical Assistance Act (AMAA) of 1998 § 5(b), 49 U.S.C. § 44701 (West Supp. 1998). Per American Airlines, flight attendants demanded indemnification prior to giving their consent to use AEDs, thus the carrier would pay any damage award. See Hotard, *supra* note 30.

⁷⁹ See *Becton, Dickinson & Co. v. Food and Drug Admin.*, 448 F. Supp. 776, 780 (N.D.N.Y. 1978). Restricted devices were formerly known as prescription devices. See *id.* at 780. The FDA determines, "in accordance with a rather subjective standard set forth in the statute, which particular medical devices should be restricted." *Id.* at 779 (footnote omitted). The *Becton* court further explained that the "theme of the 1976 Amendments call[s] for . . . collaboration from members of the industry, practitioners, and experts within the field" in determining which devices should be restricted. *Id.* at 780.

⁸⁰ See Hedges, *supra* note 67, Representative John J. Duncan, Jr., R-Tenn., the present chairman of the House Aviation Subcommittee, stated that the present level of training for flight attendants "is not much more than a basic first-aid course." Richard Powelson Scripps, *Congress Wants Details on In-Flight Emergencies*, PORT ST. LUCIE NEWS, Dec. 30, 1997, at A1.

⁸¹ See Shilling, *supra* note 21. Per Dr. Shilling, and contrary to the belief of many, a shock, irrespective of a patient's need for it, would not put the patient in a worse physical state than had the shock been omitted (it would, however, hurt a great deal).

Accordingly, an argument for "harmful effect" in the case of an AED misapplication could be made, thus requiring medical supervision. In response, an AED manufacturer's counter-arguments are: (1) misuse and resulting "harmful effects" are unlikely because the AED is very simple to use (adequate directions for its use are provided, and an AED contains its own internal diagnostic software that determines whether a shock is necessary for a particular patient); and (2) the device is not a restricted device, therefore, "harmful effects" are not an issue.

The AED's virtually "idiot-proof" operation, utilizing voice or visual prompts after attaching leads to the patient, supports a device manufacturer's argument that "harmful effects" are unlikely.⁸² The AED prompts guide the user to determine, through diagnostic software, whether or not the attendant should administer the shock. Consequently, a manufacturer will argue that specific medical knowledge or training is not required for the safe and effective operation of an AED device because adequate directions are provided to avoid "harmful effects."

C. CONSEQUENCES OF COMPLIANCE WITH FDA PROCEDURE

Compliance with the 510(k) procedure has been used as a defense in products liability actions against manufacturers.⁸³ In the past, courts have accepted this defense on the basis of federal preemption of certain state law claims.⁸⁴ The Supreme Court changed this in *Medtronic, Inc. v. Lohr*, holding that the Medical Device Amendments of 1976 do not preempt all state common law negligence claims against a device manufacturer.⁸⁵ Other courts have similarly held that because substantial equivalence focuses on equivalence and not safety, state claims are not preempted.⁸⁶ The critical distinction is whether the approval

⁸² Author Mark Fritz points out that "[t]he latest generation of supposedly idiot-proof defibrillators cost about \$3,000 and weigh five pounds." Mark Fritz, *Putting A Heart Saver In Hands of Novices*, AUSTIN AM.-STATESMAN, Aug. 7, 1998, at F3.

⁸³ See *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, *reh'g denied*, 873 F.2d 297 (5th Cir. 1989) (failure-to-warn and labeling claims of Class II medical device held preempted).

⁸⁴ See *id.* at 246.

⁸⁵ 518 U.S. 470, 501 (1996).

⁸⁶ See *Moore*, 867 F.2d at 246 (Class II devices are not subject to premarket approval, therefore claims for defective design are not preempted). See generally Sanders, *supra* note 59 (extensive discussion of the preemption issue regarding medical device products liability).

process subjected the medical device to a stringent premarket review or the lesser standard of premarket notification.⁸⁷ The general rule is if substantial equivalence was the means used to get the device on the market, certain state law claims will not be preempted by federal law because premarket review was not required.⁸⁸

V. AVIATION LIABILITY ANALYSIS AND PREEMPTION UNDER THE AVIATION MEDICAL ASSISTANCE ACT OF 1998⁸⁹

Medical care providers, because of their special relationship to their patients, are vulnerable to liability claims if they negligently choose to provide only one part of an established multi-component treatment plan in rendering aid.⁹⁰ Similarly, flight attendants, fully trained and aware of the Advanced Cardiac Life Support (ACLS) guidelines for ventricular fibrillation, *may* be liable for failure to complete their affirmative duty once they act to treat the victim.

A. AN AIRLINE'S LACK OF COMPREHENSIVE MEDICAL CARE

Air carriers make use of informed and competent medical advice, usually in the form of medical doctors as employees or consultants.⁹¹ As common carriers, airlines have a duty to provide "reasonable" medical care when the need becomes apparent.⁹²

1. *The Aviation Medical Assistance Act of 1998*

Prior to the Aviation Act, Good Samaritan laws did not shield air carriers from liability because providing reasonable care was

⁸⁷ See *Dow v. Baxter Healthcare Corp.*, 899 F. Supp. 822, 831 (D. Mass. 1995).

⁸⁸ See *Moore*, 867 F.2d at 246.

⁸⁹ Aviation Medical Assistance Act (AMAA) of 1998, 49 U.S.C. § 44701 (West Supp. 1998).

⁹⁰ The various states are replete with examples of cases claiming failure to diagnose, wrongful death, and loss of chance of survival. The state of Texas provides several recent examples. See *Eoff v. Hal & Charlie Peterson Foundation*, 811 S.W.2d 187 (Tex.App.—San Antonio 1991, *no writ*); see also *McCall v. Dallas Hospital District*, No. 05-94-01816-CV, 1995 WL 500288 (Tex. App.—Dallas, Aug. 22, 1995, *writ denied*) (survivors brought wrongful death action against hospital alleging negligent use of hospital equipment in failure to evaluate tests properly when the tests indicated that a patient had a significant and foreseeable risk of a heart attack from which he later died).

⁹¹ See *AMR Corp. Communications*, *supra* note 1. American Airlines employs Dr. David McKenas as its Corporate Medical Director. See *id.*

⁹² See RESTATEMENT (SECOND) OF TORTS § 314A (1965).

viewed as part of their duty to their passengers.⁹³ This reasonable care, while still generally applicable, now comes with the added benefit of no liability for damages. Under the Aviation Medical Assistance Act:

[A]n air carrier shall not be held liable for damages in any action brought in a Federal or State court arising out of the performance of the air carrier in obtaining or attempting to obtain the assistance of a passenger in an in-flight medical emergency, or out of the acts or omissions of the passenger rendering the assistance, if the passenger is not an employee or agent of the carrier and the carrier in good faith believes that the passenger is a medically qualified individual.⁹⁴

In addition, the new Act provides that:

[A]n individual shall not be liable for damages in any action brought in a Federal or State court arising out of the acts or omissions of the individual in providing or attempting to provide assistance in the case of an in-flight medical emergency unless the individual, while rendering such assistance, is guilty of gross negligence or willful misconduct.⁹⁵

Gross negligence or willful misconduct will be difficult to establish with respect to the actions of most Good Samaritan medical professionals. The knowledge that an air carrier or cardiac specialist possesses cannot be imputed to a general practitioner or some other non-specialist who may undertake to aid a passenger in need. Therefore, most lawsuits naming an airline will most likely result from either the absolute failure to provide defibrillators or enhanced medical kits when they were aware of

⁹³ See Aviation Medical Assistance Act § 5(a); see also Hotard, *supra* note 30. AMR's Hotard stated that American Airlines and others in the medical community were pushing for federal legislation to provide Good Samaritan indemnification for AED use by flight attendants, as well as for all participants in a medical emergency, in order to encourage Good Samaritan assistance. It seems that their push was indeed successful. Under the Act not only is an airline protected, but so is its good faith reliance on medically qualified Good Samaritans in administering emergency medical assistance. See Aviation Medical Assistance Act § 5(a). The assistance of Good Samaritan doctor-passengers is critical to an air carrier's ability to administer prescription drugs that will soon be available in the expanded medical kits. See Hotard, *supra* note 30. This new legislation indemnifying the Good Samaritan doctor-passenger may curb the negative trend of doctors refusing to assist for fear of getting sued. But the change in federal law must be disseminated in order to have this positive effect.

⁹⁴ Aviation Medical Assistance Act § 5(a).

⁹⁵ *Id.* § 5(b).

this need, given the actions taken by the industry leaders.⁹⁶ The practice of the industry may serve to raise this aspect of the standard of care for all air carriers. Under this logic, it will be no excuse that an airline can land in twenty minutes given the wide variety of sources that make it clear that the time to treat is well inside of ten minutes.⁹⁷ Other possible claims may be based on a challenge to an airline's choice to provide only one part of a multi-step emergency process when it is within their ability to provide more than mere defibrillators. This latter theory, also based on an airline's failure to perform, has a lesser chance of success under the new Act's liability shield, but this will turn on a court's interpretation of "performance."

2. *The ACLS Algorithm*

The complete ACLS algorithm for treatment of ventricular fibrillation is set forth in the medical texts. This algorithm is widely referenced and requires, in addition to defibrillation, IV access, the drug Epinephrine (administered to the patient every five minutes), intubation (to open up the airway "if possible"), and an additional repetition of drugs.⁹⁸ An airline medical kit, however, is not similarly equipped. Air carriers who venture into the realm of advanced medical emergency care by providing defibrillation do not presently supply the essential drugs that the ACLS treatment plan requires.⁹⁹ This means that passengers treated with AEDs may still die without the balance of treatment necessary.

⁹⁶ The limits on liability arise out of an air carrier's "*performance . . . in obtaining or attempting to obtain [] assistance . . . in an in-flight medical emergency.*" Aviation Medical Assistance Act § 5(a) (emphasis added). Notably, there are no limits on liability for the failure to perform. See Higher Duty Airlines, and AEDS, *infra* notes 175-76 and accompanying text.

⁹⁷ This is the position of Southwest Airlines. See J. Lynn Lunsford, *Airlines Take Initiative for Safer Flying Carriers Make Improvements Without Prodding from FAA*, DALLAS MORNING NEWS, Apr. 5, 1998, at 1A. "Our flights are of such short duration that we are rarely more than 20 minutes from an airport," therefore defibrillators are not as important as on a long-haul carrier. *Id.*

⁹⁸ See HEART DISEASE, *supra* note 19, at 776-77. "[D]efibrillation and epinephrine are more important initially." *Id.* at 777. The treatment assumes a continuation of ventricular defibrillation. After resuscitation, patients are maintained on a lidocaine infusion. See *id.*

⁹⁹ See AMR Corp. Communications, *supra* note 1. American Airlines has announced that they intend to "enhance [their] . . . [doctors only] on-board medical kit . . . by adding certain prescription medicines to treat cardiac arrest"; however, this will not solve the problem for cases when only a flight attendant is present. *Id.*

This treatment gap will soon be partially remedied. American Airlines, for example, has plans to include the essential prescription drugs in "doctors only" medical kits.¹⁰⁰ Still, the ability to administer these drugs presumes that a licensed medical professional will coincidentally be onboard when a passenger has a medical crisis.¹⁰¹ Thus, the treatment gap manifests itself in the lack of on-board medical personnel. Even if all the necessary medical equipment and medicines are present for a given in-flight emergency, without a guarantee of adequately trained medical professionals to administer the comprehensive treatment, flight attendants will soon discover that they can treat few passengers effectively. Admittedly, however, saving even a few lives is better than none.

Soon, it will be possible to eliminate this treatment gap as advanced satellite technology in the form of telemetry becomes available. The new technology will enable air carriers to transmit passenger health data to medical professionals on land who can then dictate the steps necessary to save the passenger.¹⁰² This ability to diagnose, however, does not fully address the present personnel gap. Flight attendants are not permitted to administer prescription drugs. It remains to be seen whether new laws will be enacted to permit this in some form. Until then, air carrier personnel and Good Samaritans should be encouraged to do whatever they can using the means provided by the air carriers. The reason is simple: presently, there is no potential to land a plane within the critical ten minute window. This means that timely follow-up care on the ground is not an option and cannot be relied upon by the airline or the AED manufacturer.¹⁰³ Worse yet, because of the present lack of the

¹⁰⁰ See Hedges, *supra* note 67.

¹⁰¹ American Airlines states that a surprising amount of flights have doctor-passengers on-board. See Hotard, *supra* note 30. The remaining question, however, is what are the doctors' medical specialties, which will determine their ability to aid. Nevertheless, any medical professional is better than flight attendants alone who feel, with good reason, "more like the Three Stooges than superheroes" when they are "[w]ithout the aid of a medically trained professional." Gail Todd, *Lawsuit Threats Scare Off Good Samaritans In Medical Emergencies*, CHICAGO DAILY HERALD, Aug. 9, 1998, at 3.

¹⁰² See Robert Davis, *High-tech Idea Equips Planes for Medical Crises*, USA TODAY, Aug. 28, 1997, at 9A. American Airlines has successfully tested the equipment that enables the simultaneous transmission of vital signs to doctors in hospitals. See Brown, *supra* note 1. During this test, doctors were able to "correctly diagnose 20 different medical conditions simulated on board" the flight. *Id.*

¹⁰³ See Crewdson, *supra* note 10, at 2-3. "Even under ideal conditions, . . . an emergency landing from cruising altitude takes at least 20 minutes—longer, if

complete ACLS medical supplies, neither the administration of the essential prescription drugs nor intubation is possible within the critical treatment period even if a doctor-passenger is present and volunteers.

B. IMPLICATIONS OF ONE AIRLINE'S DEFIBRILLATOR POLICY

One airline has chosen, at least initially, to restrict the use of defibrillators to over-seas, international flights.¹⁰⁴ Given the present lack of follow-up supplies on-board, passengers on those flights who require resuscitation with a defibrillator will not receive any essential prescription drugs or intubation, if needed, because the airplane does not carry these supplies, and under the most optimal circumstances, it cannot land quickly enough to get them because the airplane is over water.¹⁰⁵ This airline policy is based on the following premise: AEDs are expensive and unnecessary for short-haul, over-land flights. Emergency defibrillation will be provided only on flights that are both international and over water because on these flights it is impossible to land the plane promptly. The airline reasons that the over-land flights are potentially within twenty to forty minutes of landing; therefore, medical care can be provided on the ground, and defibrillators are unnecessary.¹⁰⁶ Sounds good, but a careful analysis of this premise reveals that, given the present limitations of on-board medical kits, the passengers who are best situated to receive both the in-flight defibrillation and the essential follow-up treatment are those passengers traveling *over-land*. Those are the passengers who presently have the opportunity both to be defibrillated and to get the requisite follow-up care *on land* within a realistic time period after the onset of fibrilla-

weather, air traffic and other factors are less than perfect—and 20 minutes is too long to wait for a defibrillator.” *Id.* The President of the Association of Professional Flight Attendants puts the timeframe at a minimum of forty minutes. See Hedges, *supra* note 67. Note that the ability to provide follow-up care is also the basis for the manufacturer’s substantial equivalence claim. But unlike the “substantially equivalent” AEDs that are used for land-based emergencies (where ambulances are only a 911 call away), airlines cannot provide the timely follow-up care required with their use of AEDs. Therefore, there is a strong argument that this difference in application—the lack of requisite follow-up care—would disqualify the AED from being “substantially equivalent.”

¹⁰⁴ American Airlines has since announced that they will equip their entire fleet with AEDs. See Brown, *supra* note 1.

¹⁰⁵ See *id.*

¹⁰⁶ See *id.* American does note that their ultimate objective is to have all planes equipped with AEDs and enhanced medical kits. See Hotard, *supra* note 30.

tion. The overseas passengers will not be able to receive the balance of the ACLS treatment plan in a timely manner; therefore, they are still at risk without the further required follow-up treatment necessary to sustain life until landing—often hours away. Consequently, it is *the over-land domestic* passengers that an airline can aid most effectively given the present limitations of both the medical kit and the medical professional. Presently, the domestic over-land passengers have the best odds of survival. They can receive timely in-flight defibrillation and the requisite prescription drugs after the plane makes a timely diversion. Ironically, some air carriers insist that these over-land, short-haul flights cannot benefit from the presence of an AED.¹⁰⁷ This failure to perform with respect to short-haul flights has the potential to form the basis of a liability claim in a court of law. This is different from an omission claim, the latter now covered under the liability limits in the new Aviation Act.¹⁰⁸ To illustrate the difference from an omission claim, a court might utilize the following jury instruction:

Question to the jury: Did the airline know or should the airline have known that defibrillation and drug therapy were critical to treating a ventricular fibrillation? Answer: Yes. Do you find that the airline in question failed to provide "advanced cardiac life support" when it affirmatively acted to aid the victim of a heart attack at 35,000 feet? You are instructed that ACLS is defined as:

Complex procedures used to restore and/or maintain breathing and circulation in a person who has experienced cardiac and/or respiratory arrest. Procedures include the administration of drugs, *electric shock*, and intubation. Compare basic life support. . . . [Basic life support is defined as t]he relatively simple resuscitative procedures used to restore and maintain breathing and circulation in a person who has experienced cardiac or respiratory arrest. Procedures include clearing the victim's airway, administering mouth-to-mouth resuscitation, manually compressing the chest to circulate blood in the absence of heart action. Compare advanced cardiac life support.¹⁰⁹

Compare a wrongful death claim based on the total absence of advanced medical care.

¹⁰⁷ See Lunsford *supra*, note 97 (statement by Southwest Airlines spokesman Ed Stewart).

¹⁰⁸ Aviation Medical Assistance Act (AMAA) of 1998 § 5(a), 49 U.S.C.A. § 44701 (West Supp. 1998).

¹⁰⁹ *Guidelines, supra* note 22, at 1-2 (emphasis added).

Question One: Do you find that the air carrier knew or should have known that defibrillation AND drug therapy were critical to treating a passenger experiencing ventricular fibrillation? *Question Two: Do you find that the air carrier FAILED TO PERFORM medical assistance when it failed to obtain or attempt to obtain the medical supplies that it was aware were necessary to treat medical emergencies and are normally supplied by the major airlines in the industry?*

VI. LEGAL PRECEDENT AND INTERNATIONAL PREEMPTION ISSUES

One justification that may have factored into an airline's decision to limit the utilization of defibrillators to over-seas international flights, aside from the obvious expense rationale, is special liability protection. This rationale seems likely when you consider that it was not until after Congress passed liability-limiting legislation in the United States that air carriers began expanding the use of AEDs to include domestic flights. Under the special liability exemptions previously carved out through international treaties, air carriers have generally enjoyed limited liability with regard to international passenger situations. The sparse case law that exists tends to side with an airline that has fulfilled its basic duty to its passengers.

A. INTERNATIONAL PREEMPTION

1. *Liability Under the Warsaw Convention*

One example of an airline's special international liability protection is the Warsaw Convention, an international treaty binding on the United States. Under the Warsaw Convention, "air carriers are liable for injuries sustained by a passenger on an international flight [only] 'if the accident which caused the damage so sustained took place on board the aircraft or in the course of any of the operations of embarking or disembarking.'"¹¹⁰

The case of *Krys v. Lufthansa* recently addressed the liability issue when the passenger suffered a non-fatal heart attack during a transatlantic flight and later alleged that the crew was negligent in failing to make an unscheduled landing in order for the passenger to receive essential medical treatment that could

¹¹⁰ *Krys v. Lufthansa German Airlines*, 119 F.3d 1515, 1518 (11th Cir. 1997) (quoting 49 Stat. 3018, Article 17 of the Warsaw Convention and "providing the official English translation of the governing French text").

have prevented some of the extensive damage done to his heart.¹¹¹ The plaintiff's suit, filed in Florida, sought damages from the airline based on the theories of negligence and loss of consortium. The defendant airline initially lost its summary judgment motion, which was based on being preempted from state liability through the Warsaw Convention.¹¹² The airline later appealed the common law negligence judgment on the same grounds.¹¹³

The Eleventh Circuit addressed the preemption issue and, quoting the Supreme Court, held that liability of an airline under the Warsaw Convention is dependent on "the passenger prov[ing] that an 'accident' was the cause of . . . injury."¹¹⁴ The meaning of the word "accident" is critical to an airline's ability to defeat a negligence claim when its defense is based on the liability limits of the Warsaw Convention.

The meaning of "accident," previously split in the courts of appeals, was resolved by the Supreme Court in the case of *Air France v. Saks*.¹¹⁵ In *Air France*, the Supreme Court held that "accident" is "an unexpected or unusual event or happening that is *external* to the passenger."¹¹⁶ The Court further explained that "when the injury indisputably results from the passenger's own internal reaction to the usual, normal, and expected operation of the aircraft, it has not been caused by an accident."¹¹⁷

In applying the above definition to the claim of negligence due to an airline's failure to make an emergency landing when presented with an in-flight heart attack, the Eleventh Circuit, in *Krys*, determined that the Warsaw Convention "provides carriers a 'due care' defense . . . turning on the absence of negligence."¹¹⁸ Ultimately, the *Krys* court held that Warsaw preemption does not "extend the term [accident] to cover routine

¹¹¹ *Id.* at 1517.

¹¹² Convention for the Unification of Certain Rules Relating to International Transportation by Air, Oct. 12, 1929, 49 Stat. 3000, T.S. No. 876 (1934).

¹¹³ See *Krys*, 119 F.3d at 1517-18.

¹¹⁴ *Id.* at 1518 (quoting *Air France v. Saks*, 470 U.S. 392, 396 (1985)).

¹¹⁵ 470 U.S. at 396.

¹¹⁶ *Id.* at 405 (emphasis added).

¹¹⁷ *Id.* at 406. One example of an accident preempted by the Warsaw Convention can be found in the case of *Fishman v. Delta Air Lines, Inc.*, 938 F. Supp. 228 (S.D.N.Y. 1996), *aff'd*, 132 F.3d 138 (2d Cir. 1998), where a child was burned by scalding water spilled by a flight attendant. The *Fishman* court granted the airline's motion to dismiss based on the injury being the result of an "accident" within the meaning of the Warsaw Convention. *Fishman*, 938 F. Supp. at 230.

¹¹⁸ *Krys*, 119 F.3d at 1522.

travel procedures that produce an injury due to the peculiar internal condition of a passenger.”¹¹⁹

Proceeding to the issue of negligent reaction to the symptoms of a heart attack, the *Krys* court responded to Lufthansa’s non-negligence defense, notably based on the crew’s deference to a Good Samaritan doctor’s assessment of the medical emergency, by stating that this reliance does not relieve the airline of the duty to exercise reasonable care. This duty of care includes monitoring the medical crisis to “see what’s happening and make sure that it’s correct, which was not done in this case, and . . . the results show what happens when the crew decides to walk away from a situation because there’s a doctor on the scene.”¹²⁰ Concluding that Lufthansa was liable for negligence “so long as the delay [in landing the aircraft] aggravated the damage to the heart,” the *Krys* court affirmed the lower court’s negligence judgment against the airline.¹²¹

2. Preemption by DOHSA

In addition to the Warsaw Convention, other preemption doctrines may serve to limit an airline’s liability. The Death on the High Seas Act (DOHSA) is one such defense. DOHSA precludes recovery for nonpecuniary damages and limits airline responsibility to monetary expenses suffered by the estate of the decedent.¹²² In order for DOHSA to apply, the death must have occurred “on the high seas beyond a marine league from the shore of any State, or the District of Columbia, or the Territories or dependencies of the United States.”¹²³

The expansive legal effect of DOHSA has also been reviewed by the Supreme Court. In the case of *Zicherman v. Korean Air Lines*,¹²⁴ the Supreme Court held that “DOHSA precluded a plaintiff from augmenting his DOHSA claims with damages

¹¹⁹ *Id.* at 1522.

¹²⁰ *Id.* at 1527. Now, of course, an air carrier’s reliance on a “medically qualified individual” would absolve that air carrier from liability. Aviation Medical Assistance Act (AMAA) of 1998 § 5(b), 49 U.S.C.A. § 44701 (West Supp. 1998).

¹²¹ *Krys*, 119 F.3d at 1528 n.25; *see also* *Gingeleskie v. Westin Hotel Co.*, 145 F.3d 1337 (9th Cir. 1998) (holding that a genuine issue of material fact exists as to whether the hotel met its duty but that the car service had no duty to take action until the condition became apparent and “we know of no duty that requires common carriers to be expert in medical diagnosis.”).

¹²² *See* *Tandon v. United Air Lines*, 968 F. Supp. 940 (S.D.N.Y. 1997).

¹²³ *Id.* at 942. In *Tandon*, the parties first disputed where the death occurred, but the pilot’s affidavit settled the matter, making DOHSA applicable. *Id.*

¹²⁴ 516 U.S. 217 (1996).

claims brought under other laws, such as state law or general maritime law."¹²⁵ This wide preemptive effect supplies one reason why an airline would initially choose to limit the use of defibrillators to over-water international flights.

DOHSA liability limits are economically enticing. This Act precludes recovery for many high-dollar damage claims such as loss of society, the anguish of survivors, and punitive damages. Even the decedent's pain and suffering is precluded on the basis that it is a plaintiff's survival claim.¹²⁶ But DOHSA limits must not be the real reason for limiting defibrillator use because that reason does not explain the fact that the first time a defibrillator was used by a U.S. airline was during the *domestic* leg of the overseas flight, despite that airline's policy to limit use to over-water international flights.¹²⁷ This application would afford none of DOHSA's protections. In addition, it would be unlikely that an air carrier would specifically instruct its flight attendants to use defibrillators only during the international legs of flights and to deny defibrillation to domestic-leg passengers. Thus, DOHSA exemptions do not support the rationale to limit AEDs to certain flights.

The real motivation may well be as simple as the need to cautiously roll-out the new service and to work out any intermediate problems, with the overall goal being to equip all planes. Still, the roll-out could have begun with the domestic legs since follow-up medical care would have been more probable. As stated above, however, the liability exposure prior to the enactment of the Aviation Act was obviously a major factor in the decision. This is ironic when you consider that the addition of defibrillators was supposedly driven by an air carrier's concerns for passenger health.

B. THE LACK OF NEGATIVE LEGAL PRECEDENT

A second motivating factor in an airline's decision not to equip its planes with AEDs may be the lack of negative legal precedent. The sparse case law that does exist on the subject of an airline's failure to provide sufficient medical assistance tends to side with the airline, provided that it has fulfilled its basic duty of care to the passenger.

¹²⁵ *Tandon*, 968 F. Supp. at 942 (citing *Zicherman*, 516 U.S. 217, 230 (1996)).

¹²⁶ *See id.* at 942-44.

¹²⁷ *See* Hotard, *supra* note 30.

For example, in the case of *Tandon v. United Air Lines*,¹²⁸ the issue was inadequate oxygen available on the plane to treat the deceased while she was suffering a heart attack during an international flight. In ruling that neither the heart attack nor the failure to provide adequate oxygen were preempted by the Warsaw Convention, the court proceeded to discuss the open issue of whether state law claims preempted recovery.¹²⁹ Declining to foreclose on this opportunity, the *Tandon* court permitted the plaintiff to amend his complaint so that the fact issue could be resolved by the court.

United Air Lines opposed the claim on the basis that it "did not have a duty to maintain the medications, etc. that [the] plaintiff alleges it was missing."¹³⁰ The court permitted the amended claim, noting that the FAA regulations only "enumerate the minimal requirements for medicine kits" and that the "[d]efendant has not presented any authority to support the idea that the airline cannot, by law, be found to have breached its duty of care once FAA regulations are met."¹³¹ This case has yet to be heard on the merits, but the applicable legal rule is settled: if an airline acted without negligence in administering care to the passenger, it will be held blameless.

But now the standard is even lower. According to the Aviation Act, an air carrier shall not be liable if it performed by obtaining or attempting to obtain medical assistance. Additionally, if a medically qualified passenger does volunteer to assist, that individual will only be liable for gross negligence or willful misconduct.¹³² This new standard insulating air carriers should remove all barriers to the total deployment of both defibrillators and expanded medical kits throughout their fleets.

The argument that assuming a higher standard of care will give rise to a higher duty simply has not received support in the courts. Other cases have held in favor of a common carrier, a

¹²⁸ 926 F. Supp. 366 (S.D.N.Y. 1996) (discussing facts of case and the theory of plaintiff); *see also* *Tandon v. United Airlines*, No. 94-CIV. 7002-DC, 1997 WL 158365 (S.D.N.Y. Apr. 3, 1997) (permitting plaintiff's amended complaint in subsequent case).

¹²⁹ *See Tandon*, 926 F. Supp. at 370 (citing *Air France v. Saks*, 470 U.S. 392, 408 (1985)). The *Tandon* court stated that the Supreme Court in *Saks* "declin[ed] to express [a] view on [the] viability of state law claims where [the] injury was not caused by an accident." *Id.*

¹³⁰ *Tandon*, 1997 WL 158365, at *1.

¹³¹ *Id.* at *1.

¹³² *See* Aviation Medical Assistance Act (AMAA) of 1998 § 5(a)-(b), 49 U.S.C.A. § 44701 (West Supp. 1998).

hotel, and a mall—all of which had adopted broad internal policies.¹³³ The respective courts held that the voluntary assumption of expanded medical treatment, without legal obligation, did not create a greater duty to the plaintiffs.¹³⁴ This principle is best explained within the concept of the duty owed by a common carrier.

C. THE AIRLINES' DUTY OF CARE

An airline's liability, in this context, will turn on whether the same special relationship and commensurate duty that is imputable to other common carriers who affirmatively act to administer emergency care to their passengers also applies to air carriers. This question can be answered by looking to the basic legal principles and considerations that most states follow.

1. *Restatement (Second) of Torts*¹³⁵

Sections 323 and 324 of the *Restatement (Second) of Torts*¹³⁶ (Restatement) provide the standard applied to cases where plaintiffs allege that a common carrier owes its passengers a higher duty of care. This legal theory has not always been successful. One example of this is the case of *Gingaleskie v. Westin Hotel Co.*, where a hotel guest who became ill and requested transportation to the emergency room died while in a shuttle service provided to the guest as transport.¹³⁷ In *Gingaleskie*, the plaintiff relied on the Restatement for her main argument in contending that the duty of a common carrier was breached by the defendant for failure to secure an ambulance.¹³⁸ The basic principle applied by the court can be found in section 323 of the Restatement:

Negligent Performance of Undertaking to Render Services. One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to

¹³³ See *Gingaleskie v. Westin Hotel Co.*, 961 F. Supp. 1310 (D. Ariz. 1997), *aff'd in part and rev'd in part*, 1998 U.S. App. LEXIS 19748 (9th Cir. Ariz. May 27, 1998) (common carrier); *Lundy v. Adamar of N.J., Inc.*, 34 F.3d 1173 (3d Cir. 1994) (hotel); *Newsome v. Cservak*, 130 A.D.2d 637 (N.Y. App. Div. 1987) (mall owner).

¹³⁴ See *Gingaleskie*, 961 F. Supp. at 1310; *Lundy*, 34 F.3d at 1173; *Newsome*, 130 A.D.2d at 637.

¹³⁵ RESTATEMENT (SECOND) OF TORTS (1965).

¹³⁶ *Id.* §§ 323, 324.

¹³⁷ 961 F. Supp. at 1310.

¹³⁸ *Id.* at 1315.

the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) the harm is suffered because of the other's reliance upon the undertaking.¹³⁹

The common carrier in *Gingaleskie* countered that it was transporting the passenger to the emergency room and asserted that the Good Samaritan statute afforded an exemption to any legal duty.¹⁴⁰ The court did not permit the defense, however, explaining that both the hotel and the car service had duties to act under section 314A of the Restatement and that the "Good Samaritan statutes do not apply to any duty created under § 314A."¹⁴¹ Section 314A provides that certain special relations give rise to a duty to aid:

(1) A common carrier is under a duty to its passengers to take reasonable action (a) to protect them against unreasonable risk of physical harm, and (b) to give them first aid after it knows or has reason to know that they are ill or injured, and to care for them until they can be cared for by others.¹⁴²

The *Gingaleskie* court then applied New Jersey law and defined the "carrier's 'legal duty of care for the passenger's safety . . . [as being] care commensurate with the risk of harm . . . ' [that] would under all the circumstances deem prudent to obviate the danger, known or reasonably . . . anticipated."¹⁴³ The court concluded that the defendant's acts were reasonable because there was no way of knowing that its passenger was having a heart attack. The holding most critical to the analysis of airline liability was that the internal policies of the plaintiff (in deciding whether to have better trained staff or not) did not create any greater duty owed to *Gingaleskie*.¹⁴⁴

The district court, however, was reversed on this point by the Ninth Circuit.¹⁴⁵ Applying Arizona law, the appellate court held that a "genuine issue of material fact as to whether Westin Hotel met its duty under § 314 . . . [because] an innkeeper or com-

¹³⁹ *Id.* at 1316 (quoting RESTATEMENT (SECOND) OF TORTS § 323 (1965)).

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 1317.

¹⁴² *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 314A(1) (1965)).

¹⁴³ *Id.* (quoting *Melicharek v. Hill Bus Co.*, 175 A.2d 238, 240 (N.J. Super. Ct. App. Div. 1961)).

¹⁴⁴ *See id.* at 1318-21.

¹⁴⁵ *See Gingaleskie v. Westin Hotel Co.*, 1998 U.S. App. LEXIS 19748 (9th Cir. Ariz. May 2, 1998).

mon carrier must take reasonable steps to care for a patron, once it is known or there is reason to know of a patron's illness."¹⁴⁶ "This includes the duty to take reasonable steps to 'turn the sick man over to a physician.'"¹⁴⁷ The hotel's "policy manual require[d] employees to call security in the event of a request for medical assistance," and this policy was not followed during the *Gingaleskie* crisis.¹⁴⁸

But, failing to follow company policy in providing care does not insulate the carrier. The issue becomes one of "reasonable action: in providing interim medical care."¹⁴⁹ It could be argued that reasonable action includes utilizing AEDs on every flight, given the new industry standard providing this interim care. Anything less could be characterized as a failure to perform reasonably.

Now, with the Aviation Act, the only apparent means to attack the standard of care is to show that the medically qualified individual was aware that the condition was cardiac and was grossly negligent.¹⁵⁰ Examples of gross negligence include abandoning treatment despite adequate medical supplies or mistreating a patient given the knowledge available to the individual rendering aid. This is unfortunate for the Good Samaritan who now will be the main target in suits for injuries arising from an in-flight medical emergency. At first glance, it appears that a gross negligence standard has the effect of encouraging passenger volunteers; however, upon realization that this Good Samaritan may be the sole avenue of legal redress, this legal exposure, albeit slight, may ultimately serve to discourage volunteerism. This point becomes clear when noting that the alternative, suing the air carrier, is foreclosed because of the absolute shield afforded air carriers and their personnel unless they fail to perform.¹⁵¹

2. *The Argument for Voluntary Assumption of a Higher Duty of Care*

The above quandary was the focus of another federal case applying New Jersey laws, *Lundy v. Adamar of New Jersey*, where the

¹⁴⁶ *Id.* at *5 (citing RESTATEMENT (SECOND) OF TORTS § 314A (1965)).

¹⁴⁷ *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 314A (1965)).

¹⁴⁸ *Id.* at *5-6.

¹⁴⁹ See *Gingaleskie*, 961 F. Supp. at 1316.

¹⁵⁰ See Aviation Medical Assistance Act (AMAA) of 1998 § 5(b), 49 U.S.C.A. § 44701 (West Supp. 1998).

¹⁵¹ See *id.*

defendant was a casino hotel in which Lundy was a guest.¹⁵² In *Lundy*, the patron suffered a heart attack, and emergency medical assistance was provided by a service contracted for by the hotel. In the service agreement, emergency aid for heart attacks was to include more than CPR. An on-duty nurse arrived on the scene and, within minutes, began performing CPR. The nurse placed an "ambu-bag over Lundy's face while" others assisted, including a Good Samaritan pulmonary doctor and a surgeon, who continued CPR.¹⁵³

At issue was the fact that the nurse failed to intubate the patron.¹⁵⁴ Intubation was among the medical treatment made possible in the contract between the casino and the medical service company. The plaintiffs alleged that the hotel breached its duty to its patron when it failed to provide for intubation during his care.¹⁵⁵ Additionally, the plaintiffs alleged that because the hotel "voluntarily assumed [a] duty" by contracting for intubation services, it had breached this duty as well.¹⁵⁶

Disagreeing, the court quoted *Restatement (Second) of Torts section 314A*, holding:

[T]he duty "to take reasonable action . . . to give . . . first aid" in times of emergency requires only that carriers, innkeepers and landowners procure appropriate medical care as soon as the need for such care becomes apparent and provide such first aid prior to the arrival of qualified assistance as [they] . . . are reasonably capable of giving. Clearly, the duty recognized in § 314A does not extend to providing all [the] medical care that the carrier or innkeeper could reasonably foresee might be needed by a patron.¹⁵⁷

Unlike the *Gingaleskie* court, the *Lundy* court afforded the nurse protection under New Jersey's Good Samaritan Act, despite the fact that she was an agent of the hotel.¹⁵⁸ The absence of existing precedent prevented the *Lundy* court from finding that the hotel's contract with the medical service agency consti-

¹⁵² 34 F.3d 1173 (3d. Cir. 1994).

¹⁵³ See *id.* at 1175-76.

¹⁵⁴ See *id.* at 1177. According to cardiologist Steven Shilling, intubation is an advanced cardiac life support technique that is very difficult to administer without proper training and plenty of practice. See Shilling, *supra* note 21. Intubation opens the airway to improve oxygen exchange, a technique commonly utilized in emergency rooms. See *Lundy*, 34 F.3d at 1177.

¹⁵⁵ See *Lundy*, 34 F.3d at 1178.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 1179 (emphasis added) (quoting RESTATEMENT (SECOND) OF TORTS § 314A (1965)).

¹⁵⁸ *Id.* at 1180.

tuted a voluntary assumption of a duty beyond the *Restatement*. This lack of precedent permitted the *Lundy* court to protect all affirmative acts taken in aid of the patron as being within the requirements of existing state law.¹⁵⁹ Additionally, the *Lundy* court distinguished between a voluntary assumption of duty to provide reasonable first aid—measures protected by the Good Samaritan Act—and the voluntary decision “to provide intubation equipment for the use of physician employees of an independent contractor who were known to be qualified to use” the equipment.¹⁶⁰ The court held that the latter was not equivalent to voluntarily providing “such equipment to strangers who volunteer assistance at the site of an emergency.”¹⁶¹

This last distinction is analogous to the airline-defibrillator context because defibrillators are to be used by trained flight attendants, making them “qualified to use” the AED. This usage can be distinguished from the special on-board medical kit that an airline provides for doctors’ use only. Thus, the airlines’s voluntary decisions “to provide . . . equipment for the use of . . . employees . . . who [are] known to be qualified to use it” eliminates Good Samaritan protections.¹⁶² Then, one might ask, why not go further and simultaneously provide the additional medical equipment needed to complete the care for cardiac problems? The answer to this is most likely greater liability exposure because of the controlled substances involved (flight attendants would not be “qualified users”), the risk of harm to the passenger (as in the case of administering overdoses), and the licensing barrier. By limiting the expanded medical kits to doctors only, the airlines limit the risk to the doctor’s gross negligence.

Interestingly, the Aviation Act only implies that airline personnel could not use these additional medical substances, but the Act does not remove the liability limits so long as it is a “medically qualified individual.”¹⁶³ This means that under the Act an airline may indeed be permitted to provide medically trained

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 1181 n.11.

¹⁶¹ *Id.*

¹⁶² *Id.* This is why the flight attendants insisted on indemnification prior to agreeing to use AEDs. See Hotard, *supra* note 30. These acts are now protected under the Aviation Medical Assistance Act of 1998; 49 U.S.C.A. § 44701 (West Supp. 1998).

¹⁶³ *Id.*

personnel who are not necessarily licensed and still enjoy the benefits of limited liability.

3. *The Restatement's Reliance Factor*

The *Restatement* gives rise to further duty of care issues. *Restatement section 323* contains a reliance component that affords a right of action to those who suffer harm "because of the other's reliance upon the undertaking."¹⁶⁴ Reliance on the existence of defibrillators is an example. The fact that there are air travelers who fly an air carrier because of their defibrillator policy is proof that this particular type of reliance exists.

Reliance gives rise to several unresolved issues in the air carrier context. For example, what happens when the defibrillator does not work for some reason and the passenger specifically chose the airline because of its ability to defibrillate? How many defibrillators must each plane have, and where should they be located to allow for the essential prompt access? If the passenger suffers harm because of a delay in treatment caused by the avoidable need to fully charge the defibrillator, will a fact issue be raised?

Under the new Aviation Act, these claims are most effective when alleged against the AED manufacturer. The airline in this situation will defend on the basis of the Aviation Act's limits on liability for omissions when undertaking to aid a passenger.¹⁶⁵ Therefore, unless the delay in treatment can be characterized as a failure to perform, the airline will be protected. The pre-Act approach was to defend on the basis of the *Restatement's* no-greater-duty rule, pointing to its limited duty of care provision.

One case that involved the above issue was *Fischer v. Northwest Airlines, Inc.*¹⁶⁶ In *Fischer*, the plaintiff's medical expert testified that the presence of a defibrillator and an adequate airway would have made resuscitation "very likely."¹⁶⁷ The airline moved for summary judgment, contending that—in the absence of negligence—proximate cause can only be established if the chances of survival were more than fifty percent. The airline argued that the plaintiff's own expert pointed out that the

¹⁶⁴ *Gingele v. Westin Hotel Co.*, 961 F. Supp. 1310, 1316 (D. Ariz. 1997), *aff'd in part and rev'd in part*, 1998 U.S. App. LEXIS 19748 (9th Cir. Ariz. May 22, 1998) (quoting RESTATEMENT (SECOND) OF TORTS § 323 (1965)).

¹⁶⁵ Aviation Medical Assistance Act § 5(a).

¹⁶⁶ No. 85-C-08432, 1990 WL 129677 (N.D. Ill. Aug. 30, 1990).

¹⁶⁷ *Id.* at *1.

chances are only that good in a hospital's coronary care unit.¹⁶⁸ The court denied the motion, holding that it was the defendant's burden to use her own medical expert to establish "as a matter of undisputed fact, that [the deceased passenger's] likelihood of survival was 25 percent or less."¹⁶⁹

What is most interesting about the *Fischer* case is that it raises the negligence issue when an attending medically qualified individual does not go beyond basic CPR in resuscitating a passenger experiencing a cardiac incident. Notably, the medical expert testified that a defibrillator alone would not have been enough without an adequate airway as well (the intubation step in the ACLS algorithm). The above expert testimony supports this Comment's main contention: defibrillators alone will not be sufficient to resuscitate many passengers experiencing a cardiac emergency.

The standard of care element has arisen in other instances where reliance was not at issue. Most courts have sided with the defendants in these cases. The legal standard only requires a person to provide "reasonable care" in situations that it has "reason to know" about.¹⁷⁰ In sum, case law indicates that airlines who adopt the use of defibrillators are not faced with any greater duty than the special relations duty which requires affirmative aid to a passenger in need of care until they can be cared for by others.¹⁷¹ Only the absence of reasonable care when the airline became aware of a passenger's need will subject an airline to liability for failure to perform. This could create a fact issue in cases where an AED fails to operate when needed.

The *Gingaleskie* court noted cases where no greater duty of care was imposed.¹⁷² One example is in the case of *Newsome v. Cservak*, where

the New York Supreme Court held that the defendant's internal policy of sanding and salting the entrance to the parking lot and

¹⁶⁸ See *id.* The physician medical expert "discussed the probabilities of a person being successfully resuscitated based on the general population. According to [the expert], in a hospital coronary intensive care unit, the chance of being successfully resuscitated ranges anywhere from 60 to 70 percent." *Id.* In contrast, "if a person is stricken on the street, and even if advanced life support is provided, the success rate drops to from 10 and 20 percent." *Id.*

¹⁶⁹ *Id.* at *3.

¹⁷⁰ *Gingaleskie v. Westin Hotel Co.*, 961 F. Supp. 1310, 1317 (D. Ariz. 1997), *aff'd in part and rev'd in part*, 1998 U.S. App. LEXIS 19748 (9th Cir. Ariz. May 22, 1998).

¹⁷¹ See *id.*

¹⁷² *Id.* at 1320.

roads of the mall did not create any basis for liability of the defendant to the plaintiff. [The *Newsome* court] stated: "This argument is meritless since there is no basis for the proposition that a party may be held liable for failing to follow a policy which it has adopted voluntarily, and without legal obligation, especially when there is no showing of detrimental reliance by the plaintiffs on the defendants following that policy."¹⁷³

The Tenth Circuit also was cited by the *Gingelieskie* court as permitting the internal policies of a defendant as evidence to show negligence, but "such policies do not alter the applicable standard of care."¹⁷⁴

4. *Higher Duty, Airlines, and AEDs*

Conceding that an airline only owes its passengers reasonable care under known circumstances, it could be argued that the airline knew that there was a risk of cardiac incidents when it undertook to treat them through defibrillation, but it ignored this risk on some of its flights by failing to perform on those flights with an AED. Certain passengers who happen to read an airline's publicity concerning adoption of a policy of in-flight defibrillation may indeed book their flights in reliance upon this service, and, in good faith believe that AEDs will be available for all flights. This scenario has the potential to become grounds for a detrimental reliance cause of action in cases where the AED was not provided. This failure to deliver could be interpreted as a failure to perform on a particular flight.¹⁷⁵

It is not yet clear whether the liability limits of the new Aviation Act will shield an airline from this type of claim when arguably, the air carrier has not "performed."¹⁷⁶ One thing is clear: given this new legislation most claims arising out of the use of AEDs will most likely be directed at the care provider or manufacturer.¹⁷⁷ Equally clear is the fact that AEDs can and do help,

¹⁷³ *Id.* at 1320 (quoting *Newsome v. Cservak*, 130 A.D.2d 637 (N.Y. App. Div. 1987)).

¹⁷⁴ *Id.* (quoting *Robinson v. Missouri Pacific Railroad Co.*, 16 F.3d 1083, 1091 (10th Cir. 1994)).

¹⁷⁵ See Aviation Medical Assistance Act (AMAA) of 1998 § 5(a), 49 U.S.C.A. § 44701 (West Supp. 1998). This argument does not factor in what performance was attempted in rendering emergency medical aid; therefore, the fact that assistance was given, despite the fact that AEDs were omitted, may provide a complete defense based on the limitations on liability of air carriers under the Act. See *id.*

¹⁷⁶ *Id.*

¹⁷⁷ See Zolkos, *supra* note 30, at 3. Zolkos's article on the creation of liability as a consequence of deployment of AEDs states that "manufacturers and purchasers

even though they will not always be effective given the present flight-attendant-to-passenger ratio. It takes little imagination to conceive of normal in-flight fact patterns where it will be difficult for the attendant to timely defibrillate passengers given the urgency required.

VII. AIRLINE RECOMMENDATIONS

Based on the above analysis, an airline's interim and future policies warrant adoption of additional medical services that may save passengers' lives. Unnecessary litigation is certain to result, but with the Aviation Act, such suits will now target product manufacturers or medically-qualified individuals who performed the emergency treatment. As noted, the act of providing expanded medical care does not, in itself, give rise to an additional duty for a particular airline. Nor does it serve to put other airlines on notice, unless, perhaps, a passenger detrimentally relies on expected performance.

Overhead reduction permeates every decision an airline makes in the offering of post-deregulation services. Most air travelers will attest readily to the reduction of in-flight services, particularly those involving personnel. These facts, combined with the unique constraints of providing in-flight medical care (including the logistics of cramped passenger cabins and the assumption that qualified medical personnel will coincidentally be on board to administer prescription drugs to ill passengers) are major challenges to the successful implementation of medical services. These challenges are problematic because supplying AEDs is the beginning of enhanced medical services and should be encouraged as a means to save lives. This policy has already received major encouragement from Congress in the form of liability limits for air carriers. Still, if the air carriers are truly committed to actually delivering medical care to passengers, they must seriously consider the addition of a trained medical professional to each flight crew to avoid overloading already overextended flight attendants.¹⁷⁸

of defibrillators must ensure that the devices are used and maintained properly if they want to reduce their exposure to liability suits." *Id.* "At the same time, if deploying [AEDs] does become commonplace—a situation that already may be developing among airlines—[those who] don't make the life-saving equipment available might find themselves subject to claims for failing to meet a new standard of care." *Id.*

¹⁷⁸ One method of providing for this service in a cost effective manner would be to quietly promote a program of free travel (or a major discount) for doctors

One way that an airline can show its true commitment to passenger health is by adding a paramedic on each flight to administer the life-saving medical supplies. There is a distinction between the level of care and expertise that a paramedic can offer as opposed to an Emergency Medical Technician—trained for several hundred hours in first aid basics—or that of a flight attendant—less equipped through similar training to deal with many advanced life support skills.¹⁷⁹ Having a paramedic on board with the requisite medical supplies would eliminate the biggest gap in an airline's attempt to administer life-saving medical care: medical expertise. In addition, the paramedic is specifically trained to administer in-flight intubation, another crucial medical service presently unavailable in-flight. Intubation is often necessary in conjunction with defibrillation. Standing alone, it is often needed to save lives in medical emergencies that do not call for the AED. Intubation is a difficult medical procedure that is further hindered by the physical constraints of an airplane cabin. This life-saving procedure is very troublesome for an experienced doctor-passenger, even if the airline supplies the proper equipment.

One last policy issue that an airline should consider when deciding whether to equip airplanes with AEDs is reliance on a defibrillator's thumbs-up reading as clearance for the continuation of flights. The existing policy of emergency diversions will still be required for all cardiac emergencies. Forgoing the necessity of diversions to seek additional medical care is not a medically sound policy. Some airlines are touting this as a cost benefit as a result of supplying AEDs. Certainly, elimination of some emergency landings will be possible. But, the above analysis counters this possibility by making it abundantly clear that even after a successful defibrillation, emergency landings will still be necessary for additional medical care absent full medical capabilities on board.

who travel frequently if they: schedule flights in advance, provide credentials that they are medically qualified, and agree to perform emergency aid if needed. With advance notice, air carriers could fill in any schedule gaps with their own medically qualified "floaters" for flights that would not be staffed by a volunteer doctor. Of course, it would take some time to accumulate a database of doctor-volunteers for such a program.

¹⁷⁹ See Julie Vargo, *Roadside ER: Souped-up Ambulances Are Rolling Hospitals That Provide Emergency Care on the Spot*, THE DALLAS MORNING NEWS, Jan. 26, 1998, at 3C. Paramedics are trained for almost 800 hours in basic first aid as well as in "more sophisticated life-saving skills such as starting an IV, esophageal intubation and suctioning, ECG recognition, defibrillation and chest decompression." *Id.*

Until complete on-board medical services are provided, Good Samaritans will continue to expose themselves to inevitable legal challenges for their humanitarian acts. True, there is protection in the form of the new Aviation Act, an Act that completely exempts air carriers from liability.¹⁸⁰ Meanwhile, AED manufacturers and medically-qualified emergency-care providers remain legally vulnerable in different degrees. Still, this risk, when balanced against the potential of saving lives that otherwise may be lost, is well worth it. The issue is one of public policy: determining where to stop providing in-flight medical care once the airline has opened its medical bags. This line-drawing presents difficult choices. It is clear that more than CPR is necessary because additional lives can be saved. But how far should the airline go before moving into the realm of med-flights?¹⁸¹

Taking advantage of future telemetry capabilities combined with on-board paramedics is the most comprehensive option. If airlines adopt this new technology as it becomes available, the present liability issues will become moot because full medical treatment of passengers will become a reality.¹⁸² This technology will equip airplanes with the capability to transmit an ill passenger's vital statistics to a trained medical professional on the ground, enabling the use of the complete ACLS algorithm under the guidance of this licensed medical care professional in tandem with full medical supplies and able assistance in the air.¹⁸³

At present, the best policy for an airline is to use defibrillators on *all* flights, especially those over land, while continuing to divert flights when the medical emergencies require immediate follow up care—irrespective of successful defibrillation—and provide qualified medical personnel aboard. Adopting any option that includes paramedic training yields air service that has truly come full-circle. This circle becomes complete when a medically trained professional accompanies all passengers as in

¹⁸⁰ Aviation Medical Assistance Act § 5(a).

¹⁸¹ Issues including do-not-resuscitate orders and lack of consent are bound to factor in even at the defibrillation level. See Amanda Christine Dake, *The Application of "Out of Hospital" Do Not Resuscitate Order Legislation To Commercial Airline Travel*, 63 J. AIR L. & COM. 443 (1998).

¹⁸² See Robert Davis, *High-tech Idea Equips Planes For Medical Crises*, USA TODAY, Aug. 28, 1997, at 9A. A computerized system has recently been created that "connects an ailing passenger to a doctor on the ground the same way a patient in an ambulance is monitored by a doctor waiting in an emergency room." *Id.*

¹⁸³ See *id.*

the past when only Registered Nurses were qualified to be flight attendants.

VIII. CONCLUSION

It is undisputed that air carriers are performing a benevolent function in attempting to fill a void by providing medical care to passengers. These efforts should be encouraged. Yet, because comprehensive treatment is not presently possible, such efforts may come at an added expense. This is because no domestic airline carries the requisite medical supplies or the medical personnel necessary to administer the full range of treatment necessary to aid a cardiac crisis. Soon, full treatment may be possible with the availability of both telemetry and enhanced medical kits. At that time, the traveling public will truly be able to rely on the benefits of in-flight medical care. But there is one caveat: none of this will matter if there is nobody on-board with the requisite medical training.